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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,393	10/26/2001	Joel S. Hochman	Athena1	9804

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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	SW

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,393	HOCHMAN ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed December 8, 2003. The Examiner acknowledges the amendments to the specification and to claims 1, 6, 7, 9, 13 and 14. Claims 1-15 are pending.

Claim Objections

2. Claim 7 is objected to because of the following informalities: in line 3, --delivery-- apparently should be inserted following "medication." Appropriate correction is required.

3. Claim 9 is objected to because of the following informalities: in line 4, --delivery-- apparently should be inserted following "medication." Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a means for wirelessly altering a transducing sensor, does not reasonably provide enablement for a stimulating means programmed to alter a transducing sensor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The paragraph spanning lines 5-11 of page 10 of the specification provides that the combination controller and transceiver includes means for altering the operational settings of a probe unit that is provided with a transducing sensor. However, the paragraph spanning lines 12-19 of page 10 of the specification provides the disclosure pertaining to the stimulating means recited in claim 9, and fails to teach or suggest that the stimulating means has any effect on or relation to a transducing sensor.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobozev ('199) in view of Eini et al. ('037).

Kobozev teaches a mucous membrane stimulator for transducing and affecting mucous membrane conditions within the vagina (last sentence of abstract; col. 5, lines 7-10; col. 7, lines 52-54). The stimulator forms a single, separate unit in the form of a portable, non-implanted, intravaginally containable combination probe, transceiver and power source. The stimulator is provided with a housing or casing **12**; means for sensing vaginal conditions such as pressure, pressure gradient, pH, acoustics, temperature, biopotential and conductivity (col. 7, lines 1-5); and a transceiver formed by control unit **18**, transmitter **14** and receiver **22**. The transceiver transmitter forms a means for delivering signals; electrodes form a means for stimulating nerves,

organs and surrounding tissue; and medicinal preparation coatings on the electrodes form a means for delivering medication. The transceiver is provided with 2-way wireless communication means for transmitting information that is transduced to an external unit and for receiving control and programming signals from an external unit. A wireless signal feedback loop is provided between the external units and the probe which may be an interactive or closed signal feedback wireless loop. The external units are configured to wirelessly alter the operation settings of the stimulator probe. The sensors for transducing pressure or pressure gradients inherently can form a muscular contraction sensor. The stimulator probe is a sealed unit within the housing or casing **12**. The sensors for transducing pressure, pressure gradient, pH, acoustics, temperature, biopotential and conductivity are capable of detecting changes in the vaginal environment. The external units form means for wirelessly altering stimulation signal levels, the transducing sensors, and medication delivery. The stimulator probe includes means for automatically adjusting stimulation levels in response to sensed changes in the environment (col. 4, lines 10-17; col. 6, lines 34-42) of the stimulator probe. Kobozev teaches all of the limitations of the claims except that the external units that transmit signals to the stimulator probe and that receive transduced signals from the stimulator probe are a combination controller and transceiver that forms a single hand-held unit.

Eini et al. teach a system **50** including an intravaginal device **10** for electrically stimulating and for sensing electrical activity of muscles and nerves defining the intravaginal cavity. The device includes a separate, portable, non-implanted, intravaginally containable combination probe **10** and transceiver **20** that is provided with means for sensing vaginal conditions and stimulating perineal musculature and nerves. The combination probe and

transceiver is provided with 2-way wireless communication means **26/28** for transmitting information that is transduced and for receiving control and programming signals. The system **50** further includes a single, separate unit in the form of a combination controller **52** and transceiver that is provided with wireless means **54/58** for sending signals to the probe and for receiving signals therefrom. A wireless signal feedback loop is provided between the controller and the probe. The controller **52** includes means for wirelessly altering operation settings of the probe. The probe is a sealed unit that is provided with means for transducing changes in the vaginal environment in the form of a muscle contraction sensors and stimulators **24**. The combination controller and transceiver can be a hand-held unit that can wirelessly alter stimulation signal levels at the probe. The stimulators on the probe include means for automatic adjustment of stimulation levels in response to sensed muscle contractions and changes in the vaginal environment and can be programmed to provide increasing stimulation over a given period of time. The controller and probe transmit signals to and/or receive signals from external devices **56**, such as a personal computer. In operation, the probe is inserted intravaginally such that the probe senses vaginal conditions and stimulates perineal musculature and nerves. The separate controller then uses 2-way wireless communication means to send signals to the probe and to receive signals therefrom such that a wireless signal feedback loop is provided between the probe and the controller.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the external units of a system similar to that of Kobozev as a single unit combination controller and transceiver in view of the teachings of Eini et al. in order to provide a convenient and integral extracorporeal unit that enables accurate processing of

information from the sensors, as well as processing and storing of information collected from several sessions conducted over any period of time.

Response to Arguments

8. Applicant's arguments, filed December 8, 2003, with respect to the objections to the drawings, specification and claim 2; the claim rejection of claim 6 under 35 USC 101; and rejections of claims 14 and 15 under 35 USC 112, second paragraph, have been fully considered and are persuasive. The objections to the drawings, specification and claim 2; the claim rejection of claim 6 under 35 USC 101; and rejections of claims 14 and 15 under 35 USC 112, second paragraph, have been withdrawn.

9. Applicant's arguments with respect to the rejections of claims 1-15 under 35 USC 102(b) and 102(e) have been considered but are moot in view of the new ground(s) of rejection.

Regarding the rejections of claims 1-4 and 6-15 under 35 USC 102(e) as anticipated by Eini et al., Applicant contends that Eini et al. teach a combination probe, transceiver unit and power source that is formed by two separate units rather than a single unit as claimed in the present invention. When considered in this light, the system of Eini et al. is formed by three separate units when the combination controller and transceiver is considered, rather than as a two-unit system as in the present invention. Applicant further contends that the probe, transceiver and power source of Eini et al. are not fully intravaginal. Finally, Applicant argues that Eini et al. teaches away from the rigid construction of the present invention, although the

Examiner respectfully submits that the claims of the instant application do not recite a rigid construction.

Regarding the rejections of claims 1, 2, 4-6, 11, 12, 14 and 15 under 35 USC 102(b) as anticipated by Frohn, Applicant contends that the device of Frohn is not intravaginally containable, but rather is required to be introduced into the uterus. Applicant further contends that Frohn does not teach a device that meets the "non-implanted" requirement of Applicant's claims 1 and 14, although the Examiner respectfully submits that no "non-implanted" requirement is set forth in claim 14. Finally, Applicant argues that Frohn does not provide means for "receiving control and programming signals" as required by Applicant's claims.

These arguments are moot in view of the new grounds of rejection citing Kobozev, which teaches a single unit, combination probe, transceiver and power source that is insertable into the vagina, and Eini et al. set forth hereinabove.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marty ('683) teaches a vaginal stimulator and device for the treatment of female urinary incontinence. Lesho et al. ('076) teach a continuously transmitting, temperature monitoring pill.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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February 10, 2004